REMARKS SECTION

STATUS OF THE CLAIMS

Claims 2,4,6,8 and 11 are pending in the application.

Claims 2,4,6,8 and 11 were rejected under 35 USC§102(e) as being anticipated by Harish et al. '437, and claims 2,4,6 and 8 were rejected as being anticipated by Durgin published application No. US 2002/0052653 A1 (Durgin).

Claim 2 (previously amended) and Claim 11 (previously presented) are further amended by this Amendment D.

Following entry of this Amendment D, Claims 2 (currently amended), 4,6,8 and 11 (currently amended) remain pending in the application.

SUMMARY OF THE INVENTION

A hybrid medical implant is presented wherein the hybrid implant has a biocompatible, nonabsorbable core portion and a textured outer surface portion overlying the core portion. A portion of the outer surface portion of the hybrid implant includes a plurality of discrete biocompatible and bioabsorbable particles partially embedded in the core portion. The hybrid implant is useful as a prosthesis for tissue augmentation and/or reconstruction. The core portion of the implant includes a body formed from a nonabsorbable, biocompatible implantable material such as silicone or urethane elastomer. The core portion may be either a solid body, a viscous gel body or a fluid-filled shell. The textured outer surface portion envelops the core portion and presents an irregular, textured surface to the exterior environment. The irregularities in the outer surface are due to the

plurality of bioabsorbable particles partially embedded in a nonbioabsorbable elastomer comprising the outermost surface of the implant and projecting outwardly from the outermost surface of the nonbioabsorbable elastomer. Since the bioabsorbable particles are embedded in the (nonbioabsorbable) core, after disintegration of the bioabsorbable particles due to bioabsorption thereof by the host's body following implantation therein, the character and topography of the outer surface changes, leaving a plurality of craters in the outer surface where the particles were partially embedded. The irregular topography of the outer surface of the hybrid implant in accordance with the present invention changes following implantation.

The Rejection Under 35USC§102

Claims 2,4,6,8 and 11 were rejected under 35 USC§102(e) as being anticipated by Harish et al. '437, and claims 2,4,6 and 8 were rejected as being anticipated by Durgin published application No. US 2002/0052653 A1 (Durgin). Briefly, Harrish et al. '437 disclose an implantable device having "depots" formed in an outer surface thereof. The device includes a rough or textured outer surface having pores or "depots" therein that are coated with a polymer (not particles) in a novel manner to fill the depots and reduce the presence of air bubbles in the depots. Accordingly, in accordance with Harish, the depots must be formed by physical or chemical means prior to the introduction of a biodegradable polymer/solvent composition into the depots. The polymer/solvent composition is not a plurality of discrete particles embedded in the outer surface of the core portion but a fluidic biodegradable composition that is applied uniformly to the outer surface thereof by dipping

or spraying in order to fill the depots with the composition. This is set forth in '437 col. 8, lines 45-47.

In contrast, the present invention discloses and claims a medical implant comprising a fluid-filled, nonbioabsorbable core enveloped by an outer shell that comprises a flexible nonbioabsorbable, nonporous elastomer, such as silicone elastomer, wherein the nonbioabsorbable elastomer has a plurality of bioabsorbable particles embedded therein and projecting outwardly from the outer surface of the outer shell and presenting an irregular topography. Claim 2 (currently amended) recites the process or method used for making the hybrid implant. The method disclosed for adhering bioabsorbable particulates to an outer shell having an uncured silicone outer surface provides a medical implant having the structural and functional features recited in Claim 2 (currently amended). Prior art methods involving the incorporation of a plurality of discrete particulates into the outer surface of an implant in the manner disclosed in the present invention further include the step of dissolving such particulates out of the outer surface prior to implantation thereby creating a plurality of depots in the outer surface of the resultant implant that permit tissue ingrowth. Anticipation under 35 USC§102 requires that the cited references demonstrate each and every element of the claimed invention. In view of the differences between the elements of the present invention (i.e., the application of discrete particles to the outer surface), and those of the prior art (the applicatioin of a fluid coat to the outer surface) presented herein, it is requested that this rejection be withdrawn.

Claims 2,4,6 and 8 were rejected under 35 USC§102(e) as being anticipated by Durgin; published application No. US 2002/0052653 A1 (Durgin). Again briefly, Durgin discloses an implant and a catheter operable for deploying the implant within the body. An

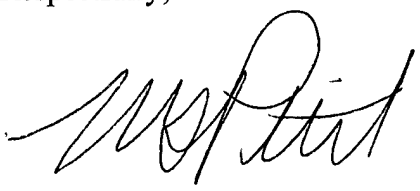
embodiment of such an implant comprising bioabsorbable anchors 32A is shown in Figure 12, and described in paragraph [0056]. Applicant respectfully disagrees with the examiner's assertion that Durgin teaches that the plurality of particles are embedded in the core portion. In Durgin, the anchors 32A are affixed to the outer surface of the implant. The purpose of the anchors 32A is to promote tissue ingrowth (between and around the anchors 32A) to prevent migration of the implanted device. There is no teaching in Durgin that the anchors 32A are embedded within the outer surface in such a manner that following implantation thereof a crater or "depot" will be formed.

The purpose of the bioabsorbable particles that are embedded in the outer surface of the present invention is initially to present an outer surface having an irregular topography (the exposed, non-embedded portion of the bioabsorbable particulates projecting outwardly from the outer surface) to disrupt the structural organization of an autogenic capsule formed therearound following implantation and thereby reduce or prevent the contracture of the capsule. After implantation, the particles are slowly biodegraded to form a plurality of craters in the outer surface of the implant which further disrupts the alignment of proteins comprising a capsule that forms around the implant.

As stated above in the discussion of Harish et al., in order for a patent to qualify as a reference supporting a §102 (b) rejection, it must disclose each and every limitation of the rejected claim. It is settled that even only slight differences between the compared inventions prevent a rejection based on lack of novelty under §102. Anticipation under 35 USC§102 requires that the cited references demonstrate each and every element of the claimed invention. In view of the differences between the elements of the present invention and those of the prior art presented herein, it is requested that this rejection be withdrawn.

Entry of this amendment, reconsideration, favorable action and early allowance and publication of this application are respectfully requested. If there are any minor matters remaining, it is respectfully requested that the examiner contact the undersigned by phone so that possible minor changes may be discussed in order to expedite the prosecution of this case.

Respectfully,



Michael G. Petit, Reg. No. 30,795
P. O. Box 91921
Santa Barbara, CA 93190-1929
Tel: 805-563-6556/Fax: 805-563-6615

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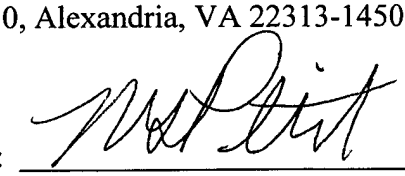
by: 

Michael G. Petit